UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON AT SEATTLE

FAIRHAVEN HEALTH, L.L.C., a Washington limited liability company, Plaintiff, v. HILIN LIFE PRODUCTS, INC., a New Jersey corporation, Defendant.	Civil Action No. PLAINTIFF'S COMPLAINT FOR VIOLATION OF THE LANHAM ACT, VIOLATION OF THE WASHINGTON STATE CONSUMER PROTECTION ACT, AND PATENT MISMARKING JURY DEMAND REQUESTED

COMES NOW Plaintiff FAIRHAVEN HEALTH, L.L.C. ("Fairhaven") in the above-referenced action, and by way of Plaintiff's Complaint for Violation of the Lanham Act, Violation of the Washington State Consumer Protection Act, and Patent Mismarking, contends, alleges, and prays as follows:

PARTIES AND JURISDICTION

I.

Fairhaven is a Washington State limited liability company, with its principal place of business in Bellingham, Washington.

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II.

Defendant Hilin Life Products, Inc. ("Hilin") is a New Jersey corporation, whose principal place of business is Newark, New Jersey.

III.

This Court has subject matter jurisdiction under 28 U.S.C. § 1331 based upon Fairhaven's federal claims, and alternatively, under 28 U.S.C. § 1332, as the parties are citizens of different states, and Fairhaven seeks in excess of $75,000.00. This Court has jurisdiction over Fairhaven's state law claim under 35 U.S.C. § 1367.

IV.

This Court has personal jurisdiction over Hilin, as it is involved in substantial, continuous, and systematic activities in the state of Washington, including, but not limited to, the marketing and sale of its product on its interactive website www.knowhen.com.

V.

Venue is proper in this Court under 28 U.S.C. § 1391.

FACTS

VI.

Fairhaven restates and incorporates by reference the allegations and contentions set out in paragraphs I-V herein.

VII.

Fairhaven markets and sells a variety of fertility, pregnancy, and nursing products. One such product is sold under the brand name "Fertile-Focus," which is a personal ovulation microscope intended to be used to predict a woman's ovulation cycle. The Fertile-Focus is

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used by placing saliva on a lens and then examining it after it dries for characteristics that indicate an increased estrogen level, which can be associated with ovulation. Fairhaven's Fertile-Focus product is one of its leading products.

VIII.

Hilin markets and sells a saliva ovulation monitor called "Knowhen" that directly competes with Fertile-Focus. Knowhen was originally marketed and sold under the name "Maybemom" by a predecessor of Hilin. Based upon knowledge and belief, Maybemom submitted what is commonly referred to as a 510(k) Summary to the United States Food and Drug Administration ("FDA") on November 12, 2002. Such summary was submitted because at the time, the classification of product was required under pertinent regulations to show that it was at least as safe and effective to a product that was already legally marketed.

IX.

In its 510(k) submission, Maybemom sought to establish that its saliva-based ovulation monitor was "substantially equivalent" to the Clear Plan Easy Ovulation Test (Unipath Diagnostics Company), which was a urine-based test. In the submission, Maybemom maintained that its product was "identical or similar to its predicate in terms of: intended use, risk to user, result interpretation (positive or negative for impending ovulation), test availability (OTC), and clinical performance (ability to identify impending ovulation.)" In seeking such approval, Maybemom reported its findings as follows:

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> In a consumer use study with 93 pre-menopausal women aged 13 to 53, the MAYBE? MOM® Mini Ovulation Microscope was 97% accurate in identifying the impending ovulation as compared to a urinary LH kit. Salivary fern ing was identified within 48 hours pre or post of the first day of the LH surge in 92/95 cycles.
>
> The readability of the MAYBE? MOM® Mini Ovulation Microscope was validated in 28 untrained woman. The consumers were able to identify salivary fern ing on at least one of the days when a trained reader identified fern ing in 25 of 28 cycles.

A true and correct copy of Maybemom's 510(k) submission is attached hereto and incorporated by reference as Exhibit A. Based upon knowledge and belief, Knowhen has differences from Maybemom, including, but not limited to, the nature of the lenses used and the inclusion of an automatic backlight.

X.

After the introduction of Maybemom, and before introduction of Fertile-Focus and Knowhen, the FDA amended its regulations, and exempted luteinizing hormone test systems from the premarket notification procedures of FDA regulations which were applied to Maybemom. 21 C.F.R. § 862.1485. Thus, no FDA notification of any kind was required for Fertile-Focus or Knowhen.

XI.

On or about February 21, 2008, Hilin sent a cease and desist e-mail to Fairhaven, demanding that it cease marketing and selling Fertile-Focus, based upon an allegation that it infringed U.S. Patent No. 5,572,370 ("'370 Patent"), and that it had the rights to the '370 Patent. Based upon knowledge and belief, Hilin has no right, title, or interest in the '370 Patent or any other patent that covers Knowhen.

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XII.

As part of its marketing and sale of Knowhen, Hilin has made numerous statements in commercial advertising or promotion about the product, which are false statements of fact, including, but not limited to, the following statements currently made on the website www.knowhen.com:

A. "The Knowhen® Saliva Fertility Monitor is the only US Clinically tested and FDA cleared product." This is a false statement of fact, including, but not limited to, for the following reasons: (1) Knowhen has never been subject to any FDA review process and is thus not a "cleared product"; (2) Knowhen is exempt from premarketing reporting to the FDA, and therefore there is no need to have FDA review or "clearance"; (3) to the extent the statement refers to the Maybemom FDA 510(k) submission, the tests subjected to Maybemom were nonclinical consumer use tests, and based upon knowledge and belief, there have been no "clinical" tests performed on Knowhen; and (4) the product Ovulook™ Ovulation Tester, a saliva-based ovulation detector, received approval from the FDA for sale under a 510(k) submission on December 5, 2001.

B. "Would you like to know whether you can conceive and when would be the best time to do that? Thanks to the development of a simple, easy-to-use device, now you can." This is a misstatement of fact, in that a saliva-based ovulation test cannot identify whether a woman can conceive.

C. "You benefit from using the Knowhen® if you:….are a couple who want to enjoy your sex life naturally without fear of conception….are premenopausal women who don't want a surprise pregnancy….Prefer 'Freedom of Choice and Peace of Mind' when it

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comes to family planning." According to the FDA, saliva-based ovulation tests should not be used to help prevent pregnancy because they are not reliable for that purpose.

D. The "Knowhen® Saliva Fertility Monitor is a handheld mini-microscope that monitors a woman's ovulation using just a single drop of saliva each morning." This is a misstatement of fact, in that a saliva-based ovulation test does not test for the occurrence of ovulation, and does not monitor ovulation. Instead, it only indicates the levels of estrogen, which aid in predicting, not monitoring, ovulation.

E. "Knowhen is the ONLY saliva-monitoring ovulation device with 98% clinically proven accuracy…." This is a false statement of fact, including, but not limited to, for the following reasons: (1) based upon knowledge and belief, Knowhen has not been subjected to any clinical studies; (2) to the extent that this statement is based upon the Maybemom FDA 510(k) submission, testing of Maybemom was not clinical; and (3) to the extent that this statement is based upon the testing of Maybemom, the tests for its FDA 510(k) submission did not result in a conclusion that the product was 98 percent accurate.

F. "Nature gave women the code to their unique ovulation cycle in their saliva. Now for the first time ever, that secret has been harnessed with the KNOWHEN® Saliva Fertility Monitor." This is a misstatement of fact, in that there was a host of saliva-based ovulation tests prior to Knowhen's release, including Maybemom, Fertile-Focus, and Ovulook™ Ovulation Tester.

G. "The KNOWHEN® Saliva Fertility Monitor is the most accurate product of its kind and lets you know when you are ovulating." This is a misstatement of fact, in that saliva-

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based ovulation tests do not identify when a woman will ovulate, but merely identify a rise in estrogen levels which can be used to predict a period of ovulation.

H. "It [KNOWHEN®] is the only such device that has been clinically proven to be 98% accurate…." This is a misstatement of fact, including, but not limited to, for the following reasons: (1) based upon knowledge and belief, Knowhen has not been subjected to any clinical studies; (2) to the extent that this statement is based upon the Maybemom FDA 510(k) submission, the testing of Maybemom was not clinical; and (3) to the extent that this statement is based upon the Maybemom FDA 510(k) submission, testing of Maybemom did not result in a conclusion that the product was 98 percent accurate.

I. "Unlike other ovulation testers on the market, this monitor uses saliva instead of urine or a thermometer." This is a misstatement of fact, in that there is a host of other saliva-based ovulation tests on the market that do not use thermometers.

J. "Our Saliva Fertility Tester is FDA certified and the only product of its kind clinically proven to be 98% effective." This is a false statement of fact, including, but not limited to, for the following reasons: (1) Knowhen product has never been subject to any FDA review process and is thus not a "cleared product"; (2) Knowhen is exempt from premarketing reporting to the FDA, and therefore there is no need to have FDA review or "clearance"; (3) to the extent the statement refers to the Maybemom FDA 510(k) submission, the tests subjected to Maybemom were nonclinical consumer use tests; (4) based upon knowledge and belief, Knowhen has not been subjected to any clinical studies; and (5) to the extent that this statement is based upon the Maybemom FDA 510(k) submission, the tests did not result in a conclusion that the product was 98 percent accurate.

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K. "Helen Denise is the originator of the category and creator of the latest breakthrough product, the KNOWHEN® Saliva Fertility Tester." This is a misstatement of fact, in that the "category" of product, i.e., saliva-based ovulation testers, had been on the market before Ms. Denise entered the industry.

L. "In 2000, her company sponsors the first ever U.S. clinical study in compliance with FDA requirements to test the effectiveness of its Mini Ovulation Microscope Saliva Fertility Monitor versus a urine-based ovulation tester." This is misstatement of fact, including, but not limited to, for the following reasons: (1) the testing performed on Maybemom was not "clinical"; and (2) the Ovulook™ Ovulation Tester, a saliva ovulation detector, received approval from the FDA for sale under a 510(k) submission on December 5, 2001, based upon a comparison of its effectiveness with a urine test.

M. "In 2002, a 98% accuracy rate is achieved [on the Maybemom]." This is a misstatement of fact, as the results from the consumer use study for Maybemom showed it to be "97% accurate in identifying the impending ovulation as compared to a urinary LH kit."

N. "Patented." This is a misstatement of fact, in that based upon knowledge and belief, there are no patent rights covering or protecting the Knowhen product.

O. "Several clinical trials have been done on the KNOWHEN® medical device and all results show a 98% accuracy on the day of ovulation to show a fern pattern appear on the microscope." This is a misstatement of fact, including, but not limited to, for the following reasons: (1) a saliva-based ovulation test is not a "medical device"; (2) based upon knowledge and belief, Knowhen has not been subjected to clinical testing; (3) to the extent this is a reference to the Maybemom 510(k) submission, there was no clinical testing, and the results

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showed it to be "97% accurate in identifying the impending ovulation as compared to a urinary LH kit."

P. "In saliva, these salts take the shape of ferns under the 60x magnification of the KNOWHEN® mini-ovulation microscope." (Current website www.knowhen.com). "KNOWHEN® contains a saliva fertility monitor that magnifies your saliva 52 times to determine the fertile and infertile days of your ovulation cycle." (Statement from website www.knowhen December 6, 2013). Based upon knowledge and belief, the lens strength of the Knowhen product has not changed between 2013 and today. One of the two statements is a misstatement of fact as the lens has to have one of the two magnification levels.

A true and correct copy of screen shots from the website www.knowhen.com website with these statements is attached hereto and incorporated by reference as Exhibit B. These and other statements made by Hilin were made in commercial advertising or promotion, and were false statements of fact.

XIII.

Hilin and Fairhaven are direct commercial competitors, and Knowhen and Fertile-Focus directly compete with each other. The products are marketed and sold to the same class of consumers, and share common distribution and advertising channels.

FIRST CAUSE OF ACTION – FALSE ADVERTISING IN VIOLATION OF THE LANHAM ACT

XIV.

Fairhaven restates and incorporates by reference the allegations and facts contained in paragraphs I-XIII herein.

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XV.

Statements made by Hilin, including, but not limited to, those set out in paragraph XII, all of which are incorporated herein by reference, were made in commercial advertising or promotion and were false statements of fact about the Knowhen. The misrepresented products travel in interstate commerce. These statements actually deceive or are likely to deceive and harm a substantial segment of the intended audience. The deception arising from these statements is material and likely to, and intended to, influence purchasing decisions. These statements made by Hilin have caused, and will continue to cause, Fairhaven to suffer damages in an amount to be determined by the trier of fact herein, and violate the Lanham Act, 15 U.S.C. § 1125(a)(1)(B). The statements made by Hilin have caused competitive injury to Fairhaven, and in their ability to compete with Hilin, and diverted potential and/or actual business from Fairhaven.

XVI.

Fairhaven is entitled to all relief afforded by 15 U.S.C. § 1117, including, but not limited to, recovery of attorneys' fees and costs, and enhanced damages. Fairhaven is entitled to equitable relief in the form of an injunction to prohibit further use of the misstatements.

SECOND CAUSE OF ACTION – VIOLATION OF THE WASHINGTON STATE CONSUMER PROTECTION ACT, RCW CHAPTER 19.86

XVII.

Fairhaven restates and incorporates by reference the allegations and facts contained in paragraphs I-XVI herein.

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XVIII.

Hilin has participated in unfair or deceptive acts or practices, including, but not limited to, those actions set out herein, all of which are incorporated herein by reference. Such acts occurred in trade or commerce and affect the public interest. Such acts have caused, and will continue to cause, Fairhaven to suffer injury to their business and/or property, including, but not limited to, the potential for diversion of sales of their own products. Such acts have caused, and will continue to cause, Fairhaven to suffer damages in an amount to be determined by the trier of fact herein. Such acts are all in violation of the Washington State Consumer Protection Act, RCW Chapter 19.86.

XIX.

Fairhaven has been, and will continue to be, damaged by Hilin's unfair trade practices, and is therefore entitled to all available relief under the Consumer Protection Act, RCW Chapter 19.86, including, but not limited to, damages, enhanced damages, injunctive relief, and an award of attorneys' fees and costs.

THIRD CAUSE OF ACTION – PATENT FALSE MARKING

XX.

Fairhaven restates and incorporates by reference the allegations and facts contained in paragraphs I-XIX herein.

XXI.

Hilin advertises, inter alia, on its website, www.knowhen.com, that its Knowhen product is "Patented." Based upon knowledge and belief, there is no patent that covers the Knowhen product, nor has Hilin obtained any license assignment or obtained any other patent

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rights that cover the Knowhen product. The representation that the product is "Patented" is therefore false.

XXII.

Hilin has used in advertising the reference to the Knowhen as "Patented" with the intent to deceive the public. Such intent is based upon Hilin's knowledge that the statement that the Knowhen is "Patented" is false and was used for the purpose of deceiving. Such knowledge and intent to deceive is evidenced by, inter alia, (1) the fact that Hilin's predecessor Maybemom sent Fairhaven a cease and desist letter alleging infringement of the '370 Patent in 2008, and then did nothing when Fairhaven refused to take such action; (2) that based upon knowledge and belief Maybemom failed to take purported action to obtain a license in the '370 Patent; (3) that Maybemom in the past sent cease and desist letters to other competitors alleging infringement of the '370 Patent, without taking any further action; and (4) that the principal of Hilin, Helen Denise, has filed a patent application as a co-inventor for a Novel Ovulation Predictor Device, which was published on November 17, 2011. Pub. No. US 2011/0282247 A1. These facts evidence knowledge of the lack of any patent rights applicable to the Knowhen product, and an intent to deceive the public to believe that such rights exist. Such actions violate 35 U.S.C. § 292.

XXIII

Hilin and Fairhaven are direct competitors for the sale of saliva ovulation tests, and their products directly compete. Hilin's intentional misstatement that the Knowhen is "Patented" has caused, and will continue to cause, Fairhaven competitive injury, including, but not limited to, lost sales and income.

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NOW, THEREFORE, having stated claims for relief, Fairhaven prays as follows:

1. that this Court grant a permanent, and where applied for a preliminary injunction against Hilin requiring it to cease all false advertising and false marking as set out herein;

2. that this Court issue an order and judgment awarding Fairhaven its damages against Hilin based upon all claims set out herein, as found by the trier of fact herein;

3. that this Court order that Hilin pay Fairhaven's costs and attorneys' fees pursuant to RCW Chapter 19.86, the Lanham Act, 15 U.S.C. § 1117, or as otherwise allowed by law, statute, or equity; and

4. that this Court award such other relief as allowed by law or equity.

DEMAND FOR JURY TRIAL

Pursuant to Fed. R. Civ. P. 38(b), Fairhaven hereby demands a jury trial.

DATED this 1st day of April, 2015.

s/ Mark J. Lee
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